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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,073

04/13/2004

Michael G. Lowery

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EXAMINER

LIU, CHU CHUAN

ART UNIT

PAPER NUMBER

3777

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,073	LOWERY, MICHAEL G.	
	Examiner	Art Unit	
	Chu Chuan Liu	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2 and 4-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Amendments to the Claims and Remarks/ Arguments submitted on 09/09/2010 are received.
2. Claims 1-2 and 4-29 are presented for examination.
3. Claim 3 is canceled.

Specification

4. The abstract of the disclosure is objected to because the length of the abstract is too long (239 words). The abstract should be in narrative form and generally limited to a single paragraph within the range of **50 to 150** words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2, 7-9, 11-18, 22-23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson *et al.* (U.S. Patent No. 5,409,471 – previous cited), further in view of Messerschmidt (U.S. Patent No. 5,823,951 – previous cited). In regard to claim 1, Atkinson discloses an article (Fig. 1) for applying a coupling agent (silicone oil, Col 2 lines 45-60) to a surface of a tissue or a body part (medical coupling site, Col 2

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lines 3-18; the article implicitly transfers an amount of silicone oil uniformly and usably to a tissue or a body part), the article comprising: a backing (foil packet 12, Fig. 1), wherein the backing comprises a non-permeable material (foil packet 12, Fig. 1); and a layer of coupling agent (silicone oil in pad 10, Fig. 1) over at least one major surface of the backing (before removing from the packet 12, Fig. 1), wherein the article is configured such that a predetermined amount (ratio of silicone oil and alcohol, Col 2 lines 54-60) of the layer of coupling agent is uniformly and usably transferrable to the surface of the tissue or the body part (the article implicitly transfers an amount of silicone oil uniformly and usably to a tissue or a body part) upon removal of the article from the tissue or the body part (Col 2 lines 6-18), wherein the predetermined amount of the layer of coupling agent enhances optical and thermal coupling between the tissue or the body part (it is well known that silicone oil is a good agent for enhancing optical and thermal coupling. Atkinson discloses a male luer but does not specifically disclose a separate optical measuring device. Messerschmidt teaches a measuring device including an optical probe (Fig. 1 of Messerschmidt) for analyzing glucose (Col 5 lines 55-60) with the use of a coupling agent on a skin surface (medium 22, Fig. 1). It is known that a coupling agent could eliminate the need for light energy to propagate through air or pockets of air due to a space between the probe and the skin surface. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to incorporate the article (Atkinson) with the optical measuring device (Messerschmidt) in order to obtain more blood related information about the tissue or body part before inserting the luer.

In regard to claim 2, Atkinson as modified by Messerschmidt discloses the coupling agent is silicon oil (silicone oil, Col 2 lines 50-57).

In regard to claim 7, Atkinson as modified by Messerschmidt discloses the backing has an area greater than an area of the layer of coupling agent (Fig. 1 of Atkinson).

In regard to claim 8, Atkinson as modified by Messerschmidt discloses the article includes a substrate layer interposed between the backing and the layer of coupling agent (the mesh fabric structure of pad 10, Fig. 1).

In regard to claim 9, Atkinson as modified by Messerschmidt discloses the substrate layer comprises a fibrous material (the mesh fabric structure of pad 10, Fig. 1 and Col 2 lines 47-49 of Atkinson).

In regard to claim 11, Atkinson as modified by Messerschmidt discloses a method for improving the precision of a non-invasive optical measurement (provides medium 22 between the probe and the surface of skin, Col 11 line 54 – Col 12 line 18 of Messerschmidt), said method comprising: providing an article (Fig. 1 of Atkinson) comprising: a backing (foil packet 12, Fig. 1 of Atkinson), wherein the backing comprises a non-permeable material (foil packet 12, Fig. 1 of Atkinson); and a layer of coupling agent (silicone oil in pad 10, Fig. 1 of Atkinson) over at least one major surface of the backing (before removing from the packet 12, Fig. 1 of Atkinson), the layer of coupling agent providing a surface on the article for contacting a tissue or a body part (Pad 10, Fig. 1 of Atkinson); contacting the article to the surface of the tissue or the body part such that the layer of coupling agent contacts the tissue or the body part (Col

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2 lines 3-6 of Atkinson); removing the article from the surface of the tissue or the body part, wherein upon the removing of the article, a specified amount of the layer of coupling agent is usably transferred to the surface of the tissue or the body part (Col 2 lines 3-11 and lines 45-60 of Atkinson); bringing an optical measuring device in contact with the usably transferred coupling agent and said tissue or said body part (Fig. 1 of Messerschmidt), wherein said usably transferred coupling agent enhances optical and thermal coupling between said device and said tissue or said body part (Col 11 line 47 – Col 12 line 18 of Messerschmidt); and performing a non-invasive determination of the concentration of an analyte in said tissue or said body part (Col 5 lines 55-60 of Messerschmidt).

In regard to claim 12, Atkinson as modified by Messerschmidt discloses the optical measurement is localized reflectance measurements (Fig. 1 of Messerschmidt).

In regard to claim 13, Atkinson as modified by Messerschmidt discloses the analyte is glucose (Col 5 lines 55-60 of Messerschmidt).

In regard to claim 14, Atkinson as modified by Messerschmidt discloses the layer of coupling agent is uniform (the ratio of the silicone oil and the alcohol is in a range of 1:2 to 1:20. The silicone oil/ alcohol mixture can form a uniform layer on the pad 10).

In regard to claim 15, Atkinson as modified by Messerschmidt discloses the layer of coupling agent is uniform (the ratio of the silicone oil and the alcohol is in a range of 1:2 to 1:20. The silicone oil/ alcohol mixture can form a uniform layer on the pad 10).

In regard to claim 16, claim 16 encompasses the same scope of the invention as that of the claims 1 and 8. Therefore, claim 16 is rejected for the same reason as the claims 1 and 8.

In regard to claim 17, Atkinson as modified by Messerschmidt discloses the coupling agent is silicon oil (silicone oil, Col 2 lines 50-57).

In regard to claim 18, Atkinson as modified by Messerschmidt discloses the backing comprises a non-permeable material (foil packet 12, Fig. 1).

In regard to claim 22, Atkinson as modified by Messerschmidt discloses the backing has an area greater than an area of the layer of coupling agent (Fig. 1 of Atkinson).

In regard to claim 23, Atkinson as modified by Messerschmidt discloses the substrate layer comprises a fibrous material (the mesh fabric structure of pad 10, Fig. 1 and Col 2 lines 47-49 of Atkinson).

In regard to claim 25, Atkinson as modified by Messerschmidt discloses the layer of coupling agent is uniform (the ratio of the silicone oil and the alcohol is in a range of 1:2 to 1:20. The silicone oil/ alcohol mixture can form a uniform layer on the pad 10).

In regard to claim 26, claim 26 encompasses the same scope of the invention as that of the claims 1 and 8. Therefore, claim 26 is rejected for the same reason as the claims 1 and 8.

In regard to claim 27, Atkinson as modified by Messerschmidt discloses the optical measurement is localized reflectance measurements (Fig. 1 of Messerschmidt).

In regard to claim 28, Atkinson as modified by Messerschmidt discloses the analyte is glucose (Col 5 lines 55-60 of Messerschmidt).

In regard to claim 29, Atkinson as modified by Messerschmidt discloses the layer of coupling agent is uniform (the ratio of the silicone oil and the alcohol is in a range of 1:2 to 1:20. The silicone oil/ alcohol mixture can form a uniform layer on the pad 10).

7. Claims 4-6 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson *et al.* (U.S. Patent No. 5,409,471 – previous cited) as applied to claims 1 and 16 above. Atkinson discloses all the elements of the current invention except for the size of the layer of coupling agent and the size of the backing. In regard to claims 4-6 and 19-20, as the Applicant has failed to provide criticality or unexpected results for the values of sizes recited in claims 4-6, it would have been within the skill of the art, through due experimentation, to realize an optimum thickness for the coupling agent layer and an optimum area of the backing, in order to provide the most accurate results.

8. Claims 10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Atkinson and Messerschmidt as applied to claims 1 and 16 above, further in view of Benecke *et al.* (U.S. Patent No. 5,008,110). In regard to claims 10 and 24, Atkinson as modified by Messerschmidt discloses all the claim limitations except the substrate layer comprises a non-fibrous material. Benecke teaches a substrate layer comprises a non-fibrous material (drug reservoir 16 which is made by porous membranes, Fig. 1 and Col 5 lines 65-68). It is well known that a porous membrane can receive and release a liquid through its surface. Therefore, it would have

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been obvious to one with ordinary skill in the art at the time of the invention was made to substitute the substrate layer (Atkinson as modified by Messerschmidt) to a porous membrane (Benecke) to obtain predictable results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chu Chuan Liu whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chu Chuan Liu/
Examiner, Art Unit 3777

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/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777